NORTHERN NEVADA ADULT MENTAL HEALTH SERVICES POLICY AND PROCEDURE DIRECTIVE

SUBJECT: INVESTIGATIONAL DRUGS

NUMBER: NN-MM-05 Page 1 of 2

ORIGINAL DATE: 06/16/90

REVIEW/REVISE DATE: 06/19/95, 01/04/01, 09/02/04, 8/2/07, 5/20/10

APPROVAL: Rosalyne Reynolds (s), Agency Director

I. PURPOSE

The purpose of this policy is to establish policies and procedures for the use of investigational drugs at Northern Nevada Adult Mental Health Services and other agencies served by its Pharmacy.

II. POLICY

It is the policy of NNAMHS that all investigational drugs will be approved for use by the Pharmacy and Therapeutics (P&T) Committee. All approvals shall be reviewed by the Pharmacy and Therapeutics Committee and reported to the Leadership Committee.

III. REFERENCE

1. NAC 639 Institutional Pharmacy Regulations

IV. DEFINITIONS

An investigational drug is one which has not received the Food Drug Administration (FDA) approval for marketing. Investigational drugs are generally in phase 3 or phase 4 clinical trials at the time of their use at this facility. This policy includes foreign drugs and other drugs which may be approved for use by the State of Nevada but not by the FDA.

V. PROCEDURE

- 1. The individual requesting permission to use an investigational medication will request approval of the Pharmacy and Therapeutics Committee. If the request is received longer than two weeks from the scheduled meeting and is considered urgent, an emergency meeting can be called.
- 2. Upon review, all approvals will be reported to Core Leadership.
- 3. The individual requesting permission will be informed of the decision of the Pharmacy and Therapeutics Committee.
- 4. Any recommendation for use of an investigational drug as part of a clinical trial will be referred to the Institutional Review Board.